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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

Civil Action No. 13-391 (ES)(SCM)

REPLY TO COUNTERCLAIMS

(Filed Electronically)

Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”), by its undersigned attorneys, for its Reply to the Counterclaims of Defendant Amneal Pharmaceuticals, LLC (“Amneal”), responds as follows:

1. Jazz Pharmaceuticals admits on information and belief the allegations of paragraph 1 of the Counterclaims.
2. Jazz Pharmaceuticals admits the allegations of paragraph 2 of the Counterclaims.
3. Paragraph 3 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that this Court has jurisdiction over the subject matter of this action concerning U.S. Patent Nos. 6,472,431 (the “431 patent”), 6,780,889 (the “889 patent”), 7,262,219 (the “219 patent”), 7,851,506 (the “506 patent”), 7,895,059 (the “059 patent”), 8,263,650 (the “650 patent”), and 8,324,275 (the “275 patent”)

pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and otherwise denies the allegations of paragraph 3 of the Counterclaims.

4. Paragraph 4 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that this Court has jurisdiction over the subject matter of this action concerning the '431, '889, '219, '506, '059, '650, and '275 patents pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and otherwise denies the allegations of paragraph 4 of the Counterclaims.

5. Jazz Pharmaceuticals admits that it has sued Amneal and Roxane Laboratories, Inc. in this District for infringement of the '431, '889, '219, '506, '059, '650, and '275 patents. Jazz Pharmaceuticals also admits that it sells Xyrem[®] in this District. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 5 of the Counterclaims.

6. Paragraph 6 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that venue is proper in this Court concerning the '431, '889, '219, '506, '059, '650, and '275 patents under 28 U.S.C. §§ 1391, and 1400(b), and 2202, and otherwise denies the allegations of paragraph 6 of the Counterclaims.

7. Paragraph 7 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that Amneal has filed counterclaims seeking a declaration of noninfringement and invalidity of the '431, '889, '219, '506, '059, '650, and '275 patents. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 7 of the Counterclaims.

8. Jazz Pharmaceuticals admits that the '431 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that

the '431 patent was duly issued by the U.S. Patent and Trademark Office on October 29, 2002, and otherwise denies the allegations of paragraph 8 of the Counterclaims.

9. Jazz Pharmaceuticals admits that it owns the '431 patent and otherwise denies the allegations of paragraph 9 of the Counterclaims.

10. Jazz Pharmaceuticals admits that the '889 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that the '889 patent was duly issued by the U.S. Patent and Trademark Office on August 24, 2004, and otherwise denies the allegations of paragraph 10 of the Counterclaims.

11. Jazz Pharmaceuticals admits that it owns the '889 patent and otherwise denies the allegations of paragraph 11 of the Counterclaims.

12. Jazz Pharmaceuticals admits that the '219 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that the '219 patent was duly issued by the U.S. Patent and Trademark Office on August 28, 2007, and otherwise denies the allegations of paragraph 12 of the Counterclaims.

13. Jazz Pharmaceuticals admits that it owns the '219 patent and otherwise denies the allegations of paragraph 13 of the Counterclaims.

14. Jazz Pharmaceuticals admits that the '506 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that the '506 patent was duly issued by the U.S. Patent and Trademark Office on December 14, 2010, and otherwise denies the allegations of paragraph 14 of the Counterclaims.

15. Jazz Pharmaceuticals admits that it owns the '506 patent and otherwise denies the allegations of paragraph 15 of the Counterclaims.

16. Jazz Pharmaceuticals admits that the '059 patent is entitled "Sensitive drug distribution system and method," that the '059 patent was duly issued by the U.S. Patent and Trademark Office on February 22, 2011, and otherwise denies the allegations of paragraph 16 of the Counterclaims.

17. Jazz Pharmaceuticals admits that it owns the '059 patent and otherwise denies the allegations of paragraph 17 of the Counterclaims.

18. Jazz Pharmaceuticals admits that the '650 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that the '650 patent was duly issued by the U.S. Patent and Trademark Office on September 11, 2012, and otherwise denies the allegations of paragraph 18 of the Counterclaims.

19. Jazz Pharmaceuticals admits that it owns the '650 patent and otherwise denies the allegations of paragraph 19 of the Counterclaims.

20. Jazz Pharmaceuticals admits that the '275 patent is entitled "Microbiologically sound and stable solutions of gamma-hydroxybutyrate salt for the treatment of narcolepsy," that the '275 patent was duly issued by the U.S. Patent and Trademark Office on December 4, 2012, and otherwise denies the allegations of paragraph 20 of the Counterclaims.

21. Jazz Pharmaceuticals admits that it owns the '275 patent and otherwise denies the allegations of paragraph 21 of the Counterclaims.

22. Amneal has withdrawn its Counterclaims concerning the '730 patent. Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 22 of the Counterclaims.

23. Amneal has withdrawn its Counterclaims concerning the '730 patent.

Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 23 of the Counterclaims.

24. Amneal has withdrawn its Counterclaims concerning the '106 patent.

Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 24 of the Counterclaims.

25. Amneal has withdrawn its Counterclaims concerning the '106 patent.

Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 25 of the Counterclaims.

26. Amneal has withdrawn its Counterclaims concerning the '107 patent.

Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 26 of the Counterclaims.

27. Amneal has withdrawn its Counterclaims concerning the '107 patent.

Accordingly, this paragraph does not require any response with respect to that patent. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 27 of the Counterclaims.

28. Jazz Pharmaceuticals admits that 21 U.S.C. § 301 *et seq.* contains statutory provisions relating to food and drugs, including applications to market new drugs, and refers to the statutes for the terms thereof. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 28 of the Counterclaims.

29. Jazz Pharmaceuticals admits that the FDA maintains the publication "Approved Drug Products with Therapeutic Equivalence," commonly called the "Orange Book," which contains patent information relating to approved drug products. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 29 of the Counterclaims.

30. Jazz Pharmaceuticals admits on information and belief the allegations of paragraph 30 of the Counterclaims.

31. Jazz Pharmaceuticals admits that the '889, '219, '506, '059, '650, and '275 patents are listed in the Orange Book and that the '431 patent is not listed in the Orange Book. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 31 of the Counterclaims.

32. Jazz Pharmaceuticals admits the allegations of paragraph 32 of the Counterclaims.

33. Jazz Pharmaceuticals admits that Amneal's ANDA contains Paragraph IV Certifications regarding the '889, '219, '506, '059, '650, and '275 patents. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 33 of the Counterclaims.

34. Jazz Pharmaceuticals admits that it filed a Complaint against Amneal alleging infringement of the '431, '889, '219, '506, '059, '650, and '275 patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 34 of the Counterclaims.

35. Jazz Pharmaceuticals admits that Amneal has asserted Affirmative Defenses and Counterclaims alleging noninfringement and invalidity of the '431, '889, '219, '506, '059, '650, and '275 patents. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 35 of the Counterclaims.

36. Paragraph 36 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 36 of the Counterclaims.

37. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 37 of the Counterclaims.

38. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 38 of the Counterclaims.

39. Jazz Pharmaceuticals admits that there is a justiciable controversy between the parties hereto concerning the '431, '889, '219, '506, '059, '650, and '275 patents. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 39 of the Counterclaims.

40. Paragraph 40 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals denies the allegations of paragraph 40 of the Counterclaims. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 40 of the Counterclaims.

41. Jazz Pharmaceuticals denies the allegations of paragraph 41 of the Counterclaims.

COUNT I

42. Jazz Pharmaceuticals incorporates by reference its replies to paragraphs 1-41 of the Counterclaims as if fully set forth herein.

43. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 43 of the Counterclaims.

44. Paragraph 44 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that Amneal has requested a declaration from this Court that it does not infringe the claims of the '431, '889, '219, '506, '059, '650, and '275 patents. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 44 of the Counterclaims.

COUNT II

45. Jazz Pharmaceuticals incorporates by reference its replies to paragraphs 1-44 of the Counterclaims as if fully set forth herein.

46. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 46 of the Counterclaims.

47. Paragraph 47 states a legal conclusion for which no answer is required. To the extent an answer is required, Jazz Pharmaceuticals admits that Amneal has requested a declaration from this Court that the claims of the '431, '889, '219, '506, '059, '650, and '275 patents are invalid. Amneal has withdrawn its Counterclaims concerning the '730, '106, and '107 patents. Accordingly, this paragraph does not require any response with respect to those patents. Jazz Pharmaceuticals otherwise denies the allegations of paragraph 47 of the Counterclaims.

AMNEAL'S PRAYER FOR RELIEF

Jazz Pharmaceuticals denies that Amneal is entitled to judgment in its favor and denies that Amneal is entitled to any of the relief set forth in its Counterclaims, Affirmative Defenses, and/or Demand for Judgment.

AFFIRMATIVE DEFENSE

FAILURE TO STATE A CLAIM

Amneal's Counterclaims fail to state any claim for which relief may be granted.

WHEREFORE, Jazz Pharmaceuticals prays for judgment in its favor on Amneal's Counterclaims and for the relief requested in Jazz Pharmaceuticals' Complaint for Patent Infringement.

Dated: July 15, 2013

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